UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

PAMELA KELLER, **Plaintiff,** **v.** **Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics, Stryker Corporation, Stryker Sales Corporation and Stryker Ireland Limited** **Defendant.**	**Case Number:** **JURY DEMAND**

COMPLAINT AT LAW AND JURY DEMAND

NOW COMES the Plaintiff, PAMELA KELLER, by and through her undersigned attorneys, complaining against Defendants HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS ("Howmedica"), STRYKER CORPORATION, STRYKER SALES CORPORATION and STRYKER IRELAND LIMITED (hereinafter referred to collectively as "Defendants"), and alleges as follows:

PARTIES

1. PAMELA KELLER is a resident of the state of Utah.

2. PAMELA KELLER was implanted with a Stryker LFIT V40™ femoral head and a Stryker ACCOLADE 2™ Stem (collectively referred to as "Hip System") in the State of Texas.

3. PAMELA KELLER's Hip System was revised in the State of Texas.

4. PAMELA KELLER suffered and continues to suffer injuries as a result of the failure of the Hip System in the State of Utah.

5. At all relevant times, HOWMEDICA was a New Jersey Corporation.

6. At all relevant times, HOWMEDICA's operations were headquartered in the State of New Jersey.

7. At all relevant times, HOWMEDICA controlled the sales and distribution of the Hip System from the state of New Jersey.

8. HOWMEDICA conducts business in the states of Utah and Texas as STRYKER ORTHOPAEDICS.

9. At all relevant times, HOWMEDICA was duly registered and/or licensed to do business in the States of Utah and Texas.

10. On information and belief, HOWMEDICA distributes or sells the Hip System from distribution facilities in the states of Utah and Texas.

11. On information and belief, HOWMEDICA applied for and received any necessary licenses to conduct business in the States of Utah and Texas.

12. At all relevant times, HOWMEDICA has been the exclusive sales agent and distributor for the Hip System in Utah and Texas.

13. Defendant STRYKER CORPORATION is a corporation organized and existing under the laws of Michigan, having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002 and conducts business throughout the United States, including the States of Utah and Texas.

14. Defendant STRYKER SALES CORPORATION is a corporation organized and existing under the laws of Michigan, having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002 and conducts business throughout the United States, including the States of Utah and Texas.

15. Defendant STRYKER SALES CORPORATION is a wholly owned subsidiary of STRYKER CORPORATION.

16. Defendant HOWMEDICA is a corporation organized and existing under the laws of New Jersey, having its principal place of business located at 325 Corporate Drive, Mahwah, NJ 07430 and conducts business throughout the United States, including the States of Utah and Texas.

17. Defendant HOWMEDICA is a wholly owned subsidiary of STRYKER CORPORATION.

18. Defendant STRYKER IRELAND LIMITED is a foreign corporation that is also a wholly owned subsidiary of STRYKER CORPORATION.

19. At all relevant times, STRYKER IRELAND LIMITED conducted research, design and/or manufacturing of the Hip System at issue in this lawsuit.

20. Upon information and belief, at all times herein mentioned, the employees of Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of the Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such allocations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of Defendants while actively engaged in the scope of their duties.

21. This products liability lawsuit seeks compensatory damages on behalf of PAMELA KELLER, who was implanted with an artificial hip replacement system using

components known as the ACCOLADE 2™ Stem and LFIT V40™ Femoral Head. These are components of the Hip System that the DEFENDANTS designed, manufactured, marketed, sold and distributed.

JURISDICTION AND VENUE

22. PLAINTIFF brings this complaint under federal diversity jurisdiction, 28 U.S.C. § 1332, because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of costs and interest. PLAINTIFF is a citizen and resident of the state of Utah. DEFENDANTS are citizens and residents of the respective states indicated above.

23. Venue is proper in the United States District Court for the District of Utah pursuant to 28 U.S.C. § 1391(a) and (c) because a substantial part wrongful acts or omissions upon which this lawsuit is based occurred in this District, DEFENDANT has substantial, systematic, and continuous contacts in this District, and PLAINTIFF is a resident of this District.

COMMON ALLEGATIONS

24. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (ball like structure at the top of the femur), rotating within the acetabulum (a cup-like structure at the bottom of the pelvis). In a healthy hip, both the femur and the acetabulum are strong, and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids. Over time, age and wear break down the cartilage. This forces the bone of the femur to rub directly against the bone of the acetabulum, and it can cause severe pain and immobility.

25. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four

separate components: (1) a femoral stem, (2) a femoral head, (3) a liner and (4) an acetabular shell. The surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball which is fixed on top of the femoral stem. The acetabular shell fits into the hip socket, with the liner locked into the shell. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

26. The Hip System implant design is more prone to in vivo corrosion and mechanical wear when implanted into a human being than hip devices manufactured by other companies.

27. The corrosion and wear debris produced by the Hip System causes the surrounding tissue to become damaged and necrotic.

28. The Hip System and related components were approved under a process by the Food and Drug Administration (hereinafter referred to as the "FDA") known as a 510(k). A 510(k) medical device does not have to go through the rigors of a clinical study to gain approval by the FDA.

29. DEFENDANTS did not conduct a clinical trial of the Hip System before putting it on the market for use in patients in the United States.

30. An article entitled, "Raised levels of metal ions in the blood in patients who have undergone uncemented metal-on-polyethylene Trident-ACCOLADE total hip replacement" was published in January of 2014. The authors of the article found high concentrations of metal in the blood of patients that had an ACCOLADE an V40 devices implanted in their body. The authors discontinued use of the products and notified DEFENDANTS of the results. DEFENDANTS has not notified patients of the results of this study or the dangers of the ACCOLADE and V40 devices.

31. Before May 14, 2012, PAMELA KELLER began medical treatment for right hip arthritis with Stefan Kreuzer, M.D.

32. Before May 14, 2012, Stefan Kreuzer, M.D., an orthopaedic surgeon licensed to practice medicine in the State of Texas, through his experience and training in the practice of medicine, indicated PAMELA KELLER met the criteria for a total hip replacement on her right hip.

33. On or about May 14, 2012, Stefan Kreuzer, M.D., implanted the DEFENDANTS ACCOLADE 2™ Stem with the LFIT V40™ femoral head into the right hip of PAMELA KELLER at Memorial City Hospital in Houston, TX.

34. At all relevant times and before the implantation of the Hip System in the PLAINTIFF, DEFENDANTS and knew that the Hip System was defective and harmful to consumers.

35. At all relevant times and before the implantation of the Hip System in the PLAINTIFF, DEFENDANTS had regular and frequent communications from surgeons who had implanted the Hip System, including PLAINTIFF's surgeon, regarding failures and complications of the Hip System.

36. Sometime after May 14, 2012, PAMELA KELLER learned that her Hip System failed and needed to be revised with another hip prosthesis.

37. On or about June 23, 2015, Brian Parsley, M.D., an orthopaedic surgeon licensed to practice medicine in the State of Texas, removed certain components of the Hip System from PAMELA KELLER and replaced them with new components at Memorial Hermann Hospital in Houston, TX.

38. As a result of the failure of the Hip System, PAMELA KELLER has been forced to undergo a series of difficult and painful revision surgeries. PAMELA KELLER suffered from dangerous post-operative infections, numerous surgeries to remove damaged or necrotic tissue, and additional surgeries to treat her for the damage caused by the toxic metal debris in her body. PAMELA KELLER's severe injuries are permanent, and her pain and limited mobility will continue for the foreseeable future.

COUNT I – STRICT PRODUCT LIABILITY AGAINST DEFENDANTS DESIGN DEFECT, MANUFACTURING DEFECT, and FAILURE TO WARN

39. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

40. DEFENDANTS had a duty to place into the stream of commerce, manufacture, distribute, market, promote, and sell the Hip System that was not defective and unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed, and sold.

41. DEFENDANTS did in fact sell, distribute, supply, and/or promote the Hip System to PAMELA KELLER and her implanting physician.

42. DEFENDANTS expected the Hip System it was selling, distributing, supplying, manufacturing, and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the states of Utah and Texas, including Plaintiff and her implanting physicians, without substantial change in the condition.

43. At the time the Hip System left the possession of DEFENDANTS and the time Hip System entered the stream of commerce, the Hip System was in an unreasonably dangerous and defective condition. These defects include but are not limited to the following:

(a) The Hip System was not reasonably safe as intended to be used;

(b) The Hip System had an inadequate design for the purposes of hip replacement;

(c) The Hip System contained unreasonably dangerous design defects, including an inherently unstable and defective design, which resulted in an unreasonably high probability of early failure;

(d) The Hip System's unstable and defective design resulted in a hip prosthesis, which had risks which exceeded the benefits of the medical device;

(e) The Hip System's unstable and defective design resulted in a hip prosthesis which was more dangerous than the ordinary consumer would expect;

(f) The Hip System failed to perform in a manner reasonably expected in light of its nature and intended function, and subjected the PLAINTIFF to an unreasonable risk of harm beyond that contemplated by an ordinary person;

(g) The Hip System was insufficiently tested;

(h) The Hip System was manufactured in a way which caused it to prematurely fail, including but not limited to having components which were not within manufacturing specifications, components which were incompatible with each other, or other manufacturing defects which would cause the system to prematurely fail;

(i) The warning to PLAINTIFF and PLAINTIFF's implanting physicians about the dangers the Hip System posed to consumers including PLAINTIFF were inadequate. The inadequacy of DEFENDANTS' warnings include, but are not limited to, the following:

i. Insufficient to alert PLAINTIFF and Plaintiff's physicians as to the risk of adverse events and/or reactions associated with the Hip System,

subjecting PLAINTIFF to risks which exceeded the benefits of the Hip System;

ii. Contained misleading warnings emphasizing the efficacy of the Hip System while downplaying the risks associated with it, thereby making use of the Hip System more dangerous than the ordinary consumer would expect;

iii. Contained insufficient and/or incorrect warnings to alert consumers, including PLAINTIFF, through their prescribing physicians regarding the risk, scope, duration, and severity of the adverse reactions associated with the Hip System;

iv. Did not disclose that it was inadequately tested;

v. Failed to convey adequate post-marketing warnings regarding the risk, severity, scope, and/or duration of the dangers posed by the Hip System;

vi. Failed to contain instructions sufficient to alert consumers to the dangers they posed, and to give them the information necessary to avoid or mitigate those dangers.

44. PAMELA KELLER used the Hip System for its intended purpose, i.e. hip replacement.

45. PAMELA KELLER could not have discovered any defect in the Hip System through the exercise of due care.

46. DEFENDANTS as designers, manufacturers, marketers, and distributors of medical devices are held to the level of knowledge of an expert in their field.

47. PAMELA KELLER and the implanting physician did not have substantially the same knowledge as the designers, manufacturers, or distributors: DEFENDANTS.

48. As a direct and proximate result of one or more of the forgoing wrongful act or omissions in the by DEFENDANTS, PAMELA KELLER was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money

for medical care in the past and in the future; furthermore, PAMELA KELLER was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

WHEREFORE, PAMELA KELLER prays for judgment against DEFENDANTS, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

COUNT II – NEGLIGENCE

49. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

50. At all times relevant, it was the duty of DEFENDANTS to exercise due care in designing, testing, manufacturing, distributing, marketing, promoting, and selling of the Hip System such that it would be reasonably safe for its intended use.

51. DEFENDANTS' negligence in the designing, testing, manufacturing, distributing, marketing, promoting, and selling of the Hip System breached the duty of care in the following ways:

a. The Hip System was negligently designed and manufactured, which caused the Hip System to release metallic corrosion which injured PLAINTIFF;
b. Creating a surgical protocol which, even when followed precisely, still resulted in the failure of the Hip System;
c. DEFENDANTS committed manufacturing errors, including but not limited to size tolerances out of specification and not within industry acceptable standards.

d. DEFENDANTS, in advertising, marketing, promoting, packaging, and selling the Hip System, negligently misrepresented material facts regarding the Hip System's safety, efficacy, and fitness for human use by claiming the Hip System was fit for its intended purpose when, in fact, it was not;

e. DEFENDANTS, in advertising, marketing, promoting, packaging, and selling the Hip System, negligently misrepresented material facts regarding the Hip System's safety, efficacy, and fitness for human use by claiming the Hip System had been adequately and reliably tested when, in fact, it was not;

f. DEFENDANTS, in advertising, marketing, promoting, packaging, and selling the Hip System, negligently misrepresented material facts regarding the Hip System's safety, efficacy, and fitness for human use by claiming the Hip System was safe and effective and was appropriate for use by human beings when, in fact, it was not;

g. DEFENDANTS, in advertising, marketing, promoting, packaging, and selling the Hip System, negligently misrepresented material facts regarding the Hip System's safety, efficacy, and fitness for human use by claiming the risk of serious adverse events and/or effects from the Hip System was comparable to that of other hip replacement systems, when in fact it was not;

h. DEFENDANTS, in advertising, marketing, promoting, packaging, and selling the Hip System, negligently misrepresented material facts regarding the Hip System's safety, efficacy, and fitness for human use by claiming the Hip System had not caused or contributed to serious adverse events and/or effects requiring the premature explants of the device when, in fact, it had.

52. DEFENDANTS knew or had reason to know that PAMELA KELLER, as a member of the general public for whose use the Hip System was placed into interstate commerce, would be likely to use the Hip System in a manner described in this Complaint.

53. DEFENDANTS knew or reasonably should have known of the danger associated with the manner and circumstances of PAMELA KELLER's foreseeable use of the Hip System, which danger would not be obvious to the general public.

54. As a direct and proximate result of one or more of the forgoing wrongful act or omissions by DEFENDANTS, PAMELA KELLER was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, PAMELA KELLER was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

WHEREFORE, PAMELA KELLER prays for judgment against defendant DEFENDANTS OSTEONICS CORPORATION, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

COUNT III – BREACH OF WARRANTY

55. Plaintiff incorporate by reference all preceding paragraphs as if fully set forth herein.

56. PAMELA KELLER currently is not in possession of any document relating to representations, warnings, and/or communications made by defendant in this action. PAMELA KELLER reserves the right to present evidence in support of the claim which is not presently in her possession, but which will be discovered in the ordinary course of litigation. Such evidence may include, but is not necessarily limited to: Instruction for Use Manuals; all written material or information provided on and/or within any and all packaging associated with PAMELA KELLER's device; manufacturer's labels, package inserts; Adverse Event Reports; clinical trial data; medical literature; medical research findings and opinions; medical publications; advertisements; sales and promotional materials; internal memoranda, emails, communications and databases; sales, prescription and adverse event report databases; and communications from DEFENDANTS in this action, including DEFENDANTS' employees, officers, directors, agents, representatives, contractors and business associates, to the public, medical community, Plaintiff's

implanting surgeon and PAMELA KELLER. Upon information, knowledge and belief, PAMELA KELLER alleges the documents, instruments and/or evidence stated above are in the possession of DEFENDANTS.

57. At the time DEFENDANTS marketed, sold, and/or distributed the Hip System, it knew that the hip device was intended for human use.

58. At the time DEFENDANTS marketed, sold, and/or distributed the Hip System, PAMELA KELLER was a foreseeable user of the device.

59. At the time DEFENDANTS marketed, sold, and/or distributed the Hip System, it expressly and/or impliedly warranted that the hip, including all of its component parts, was safe and merchantable for their intended use.

60. PAMELA KELLER and her implanting surgeon reasonably relied upon the representations that the Hip System was of merchantable quality and safe for their intended uses.

61. PAMELA KELLER used the Hip System for its intended purpose.

62. Contrary to the express and implied warranties, at the time DEFENDANTS marketed, sold and/or distributed the Hip System, it was not of merchantable quality or safe for their intended use as described above.

63. As a direct and proximate result of one or more of the forgoing wrongful act or omissions by DEFENDANTS, PAMELA KELLER was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, PAMELA KELLER was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

WHEREFORE, PAMELA KELLER, prays for judgment against defendant DEFENDANTS OSTEONICS CORPORATION, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

COUNT FOUR – NEGLIGENCE *PER SE*

64. PAMELA KELLER adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein.

65. DEFENDANTS have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warnings of the risks and dangers of the Hip System, and otherwise distributing the Hip System.

66. DEFENDANTS' acts and omissions constitute an adulteration, misbranding, or both, and constitute a breach of duty subjecting DEFENDANTS to civil liability for all damages arising therefrom, under theories of negligence *per se*.

67. PAMELA KELLER and her implanting surgeon, as a purchaser of the Hip System, are within the class of persons the laws and regulations are designed to protect and PAMELA KELLER's injuries are the type of harm these laws and regulations are designed to prevent.

68. As a direct and proximate result of DEFENDANTS' wrongful conduct, PAMELA KELLER was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; suffered device-related complications including but not limited to additional surgeries; to expend money for medical care in the past and in the future; furthermore, PAMELA KELLER was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time sustained and will continue to sustain severe physical

injuries, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, PAMELA KELLER prays for judgment against DEFENDANTS, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

COUNT FIVE – NEGLIGENT MISREPRESENTATION

69. PAMELA KELLER adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein.

70. At the time DEFENDANTS manufactured, designed, marketed, sold and distributed the Hip System for use by PAMELA KELLER, DEFENDANTS knew or should have known of the use for which the Hip System was intended and the serious risks and dangers associated with such use of the Hip System.

71. DEFENDANTS owed a duty to treating physicians and to the ultimate end-users of the Hip System, including PAMELA KELLER, to accurately and truthfully represent the risks of the Hip System. DEFENDANTS breached that duty by misrepresenting and/or failing to adequately warn PAMELA KELLER's physicians, the medical community, PAMELA KELLER, and the public about the risks of the Hip System, which DEFENDANTS knew or in the exercise of diligence should have known.

72. As a direct and proximate result of DEFENDANTS' wrongful conduct, PAMELA KELLER was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; suffered device-related complications including but not limited to additional surgeries; to expend money for medical care in the past and in the future; furthermore, PAMELA KELLER was unable to and will in the future be unable to attend to her normal affairs

and duties for an indefinite period of time sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, PAMELA KELLER prays for judgment against DEFENDANTS, in a sum in excess of jurisdictional limits of this Court, together with interests and costs of this action.

JURY DEMAND

PLAINTIFF HEREIN DEMANDS A TRIAL BY JURY.

RESPECTFULLY SUBMITTED,

By: */s/ Peter J. Flowers*

/s/ Daniel M. Singer

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